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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/505,598

02/16/2000

Arnold M. Escano

ENDOV-48232

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08/11/2004

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EXAMINER

BLANCO, JAVIER G

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/505,598

Applicant(s)

ESCANO ET AL.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 15 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 16-21, and 23-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 14, 2004 has been entered.

Election/Restrictions

2. Applicant's election of System: Species A (Figure 4); Anchor: Species A (self-expandable); and Guidewire: Species B (coiled wire) in the reply filed on May 6, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 15 and 22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 6, 2004.

Drawings

4. This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

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5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore,

(i) the “hollow cylinder extending throughout the secondary catheter and removably positioned within the contralateral member of the bifurcated graft” (see claim 22, lines 2-3) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

(ii) the “hollow metal cylinder attached within the main catheter and encompassing at least a portion of the bifurcated graft” (see claim 24, lines 2-3) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

(iii) “a cylinder slideably disposed throughout the secondary catheter and encompassing the second release wire” (see claim 35, lines 1-2) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled “Replacement Sheet” in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted

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by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

6. Claims 3 and 37-39 are objected to because of the following informalities:

- a. Regarding claim 3, please delete “the” (see line 1, second occurrence).
- b. Regarding claim 37, please substitute “down stream” (see line 2) with --downstream--.
- c. Regarding claim 37, please add a comma (--,--) (i) after “upstream vessel” (see line 2), (ii) after “first down stream vessel” (see line 2), and (iii) after “second downstream vessel” (see lines 2-3).
- d. Regarding claim 38, please add a comma (--,--) after (i) “upstream vessel” (see line 2), (ii) after “first downstream vessel” (see line 2), and (iii) after “second downstream vessel” (see line 2).
- e. Regarding claim 38, please substitute “the second” (see line 14) with --the first expandable--.
- f. Regarding claim 38, please substitute “the third” (see line 16) with --the second expandable--.
- g. Regarding claim 38, please add --bifurcated-- in front of “graft” (see line 17).
- h. Regarding claim 38, please substitute “downstream” (see line 26 and line 29) with --anchoring--.
- i. Regarding claim 39, please substitute “downstream expandable” (see line 7) with --expandable anchoring--.

Appropriate correction is required.

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Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 29, 30, and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Regarding claim 29, it is not further limiting claim 25 (see claim 25, lines 20-22). Claim 30 depends on claim 29.

b. Regarding claim 37, each of: (ii) “the first release wire” (see line 9), (ii) “the second anchoring mechanism” (see lines 9-10), (iii) “the second release wire” (see lines 10-11), (iv) “the third anchoring mechanism” (see line 11), (v) “the hollow cylindrical tube having an inner diameter less than seven millimeters along its length” (see lines 13-14), and (vi) “the snare catheter” (see line 21) lacks antecedent basis.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-14, 16-21, and 23-40 are rejected, as best understood, under 35 U.S.C. 102(b) as being clearly anticipated by Quiachon et al. (US 5,628,783).

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Quiachon et al. disclose an apparatus and method for intraluminally delivering or deploying a bifurcated graft proximate the abdominal aortic bifurcation. The system comprises a bifurcated graft (character 55) having a superior/main member (character 170), an ipsilateral tubular member (character 171), and a contralateral tubular member (character 172). The bifurcated graft further includes a superior attachment member (character 175) and ipsilateral/contralateral attachment members (character 176). Each of the attachment (= anchoring) systems is sutured to the bifurcated graft (see column 16, lines 40-43; column 17, lines 50-61).

The system further includes a capsule jacket assembly (comprising main sheath 160, which is a hollow cylindrical tube), a capsule catheter assembly 52, a balloon catheter assembly 51, a balloon 60, a guide wire 56, a contralateral guidewire 212, a distal cap 92, a distal capsule 93, a proximal (ipsilateral) capsule 132, and a contralateral capsule 202. Main sheath 160 have a length along a portion housing the bifurcated graft (see Figure 1; see column 15, lines 37-43; column 23, lines 41-46) and defines an inner diameter measuring less than seven millimeters along the length (see Figure 1; see column 12, lines 46-49; column 14, lines 34-36; column 15, lines 37-43; column 16, lines 15-21).

Quiachon et al. disclose the association of a contralateral capsule 202, a guiding tube assembly 205 (configured with a distal guiding tube 206 and a proximal guiding tube 213), and a pull wire 207 (configured with a proximal locking ball 209 and a distal locking ball 208). The contralateral capsule, the guiding tube assembly, and the pull wire are configured, in a “corresponding relationship”, to be in direct engagement (see Figures) with the contralateral

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tubular member 172 and to retain and deploy the contralateral attachment system 176 (see column 20, lines 39-47; column 21, lines 10-23; see entire document).

Quiachon et al. also disclose the association of a proximal (ipsilateral) capsule 132 and an ipsilateral locking wire 85 (configured with a proximal locking ring 86 and a distal locking ring 87) configured, in a “corresponding relationship”, to be in direct engagement (see Figures) with the ipsilateral tubular member 171 and to retain and deploy the ipsilateral attachment system 176 (see column 10, lines 53-64; column 11, lines 1-8; column 26, lines 23-39; see entire document).

11. Claims 1-14, 16-21, 23-31, 33, and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Piplani et al. (US 5,489,295).

Piplani et al. disclose an apparatus and method for intraluminally deploying a bifurcated graft 20 into a lumen formed by a wall proximate a vascular bifurcation having an aneurysm. The bifurcated graft 20 comprises main cylindrical body 112, first tubular leg 116, and second tubular leg 117. A main catheter or capsule catheter 26, having a diameter ranging from 6-9 mm, houses the bifurcated graft, a set of positioning mechanisms, and a set attaching mechanisms (see Abstract; column 2, lines 7-46; column 3, lines 7-9; Figure 1). The attaching mechanisms include expandable anchor or spring attachment means 126, 127, and 163 (having hook-like vessel engaging elements 141) attached to main cylindrical body 112, to first tubular leg 116, and to second tubular leg 117 respectively (see column 5, lines 29-67; column 10, lines 21-35; Figures 4, 8, and 17). As seen in Figure 4, each of the attaching mechanisms is attached to the graft by suture material 144 (see column 5, lines 63-67; column 6, lines 1-2). The attaching mechanisms also include a balloon catheter assembly 71 capable of expanding the expandable spring attachment means (see column 2, lines 19-34; Figures 1 and 5). The attaching mechanisms

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further include a stabilization wire 89 and a stabilization button 106 carried by the tubular member or catheter shaft 72 to constrict the expandable anchor in an unexpanded condition (see column 9, lines 2-10; Figure 5). The set of positioning mechanisms includes a main guidewire 91 configured as a stiffened rod (see Figure 1). The set of positioning mechanisms of second tubular leg 117 includes a guidewire 196 that could be removably attached to second tubular leg 117 (see column 10, lines 9-26; Figure 18), secondary catheters (capsule catheter 161 and balloon catheter 162) encompassing at least a portion of the second tubular leg 117, and an expandable spring mechanism 163 at least partially encompassed by the secondary catheter (see column 10, lines 9-35; Figure 6). The attaching mechanism of secondary catheter includes a stabilization button 216 carried by the tubular member 176 to constrict the expandable anchor 163 in an unexpanded condition (see column 10, lines 21-35; Figure 6).

Response to Arguments

12. Applicant's arguments filed January 14, 2004 have been fully considered but they are not persuasive. Applicants' arguments have been adequately addressed in the 102(b) rejections above.

Conclusion

13. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114.

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See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 703-605-4259. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB



August 5, 2004



David H. Willse
Primary Examiner